

## REMARKS

### I. Introduction

In response to the Office Action dated March 18, 2004, claims 1, 59 and 61 have been amended. Claims 1-3, 5, 8, 9, 11, 17, 19-21, 59, 61, 62, 64-66 and 71 remain in the application. Reconsideration of the application, as amended, is requested.

### II. Claim Amendments

Applicants' attorney has made amendments to the claims as indicated above. These amendments were made solely for the purpose of clarifying the language of the claims, and were not required for patentability or to distinguish the claims over the prior art.

Claim 1 was amended solely to clarify that the "critical micellar concentration" refers to the "surfactant". This amendment does not introduce new matter, and entry of this amendment is respectfully requested.

Claim 59 was amended to correct a typographical error in the term "physiologically".

Claim 61 was amended to update the reference to previous claim 59, in view of the prior cancellation of claim 60.

### III. Withdrawn Claims

At page 2 of the Office Action, the Examiner indicated that claims 1, 5, 8, 9, 11, 17, 19, 20, 59, 61, 62, 64, 65, 66 and 71 are withdrawn from consideration.

Claim 59, which was not previously withdrawn, has now been indicated as withdrawn from consideration because agent (i) was chosen to be human insulin. Applicants respectfully note, however, that agent (i) of claim 59 has not been amended since the application was originally filed, and has always read: "agent i) is selected from the group consisting of a small molecule insulin mimetic material".

Claim 20, which also had been considered within the elected subject matter, was apparently newly withdrawn because "the elected species were such that additional compounds of agent (i), (ii) or (iii) were not required". This statement is unclear to Applicants. Applicants amended claim 20 merely to clarify that "comprises two or more compounds" of an agent means "further comprising

one or more additional compounds. It is not clear how this changes the status of claim 20 as falling within or outside the elected subject matter.

Moreover, as Applicants have argued previously, merely adding a further limitation in a dependent claim cannot create a separate invention for restriction purposes. As stated in MPEP §806.03, "where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are but different definitions of the same disclosed subject matter, varying in breadth or scope of definition."

To the extent the Examiner should find any of claims 2, 3 or 21 allowable, Applicants request rejoinder of claims currently dependent from claim 1 if amended to depend from such allowed claim(s). Applicants note that the only reason previously considered dependent claims have been newly withdrawn from consideration is because they depend from claim 1, which the Examiner has withdrawn based on the deletion of "insulin" from claim 1.

#### **IV. Response to Examiner's Comments**

On page 2 of the Office Action, it is stated that the response filed 12/22/03 makes no arguments as to the validity of the previously imposed §103 rejections. For the record, Applicants wish to clarify that only claims 1-3, 9, 21, 59 and 65 were rejected under 35 U.S.C. §103 in the previous Office Action. In response, Applicants amended claims 1-3, 9, 21, 59 and 65 to introduce limitations from dependent claims that had not been rejected on the basis of prior art, but were merely objected to as dependent on a rejected claim. Accordingly, comments on the validity of the previously imposed §103 rejections would have been neither pertinent nor appropriate with respect to the amended claims.

#### **V. Non-Art Rejections**

On page 2 of the Office Action, claims 2 and 3 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection was based on the phrase "critical micellar concentration of said composition", which the Examiner indicated would more sensibly read "critical micellar concentration of said surfactant".

In response, Applicants have amended claim 1 to incorporate the Examiner's suggestion.

#### VI. Prior Art Rejections

On page 4 of the Office Action, claims 2, 3, and 21 were rejected under 35 U.S.C. §103 as being unpatentable over Walter, "Diabetes Research," 13(2):75-7 (Walter) in view of Rieveley, U.S. Patent No. 6,153,632 (Rieveley). On page (6) of the Office Action, claims 2, 3, and 21 were rejected under 35 U.S.C. §103 as being unpatentable over Grau, "Diabetes," 36(12):1453-1459, 1987 (Grau) in view of Rieveley. On page (7) of the Office Action, claims 2, 3, and 21 were rejected under 35 U.S.C. §103 as being unpatentable over Walter in view of Clark, U.S. Patent No. 5,783,556 (Clark) and further in view of Rieveley. On page (9) of the Office Action, claims 2, 3, and 21 were rejected under 35 U.S.C. §103 as being unpatentable over Walter in view of Cooper, U.S. Patent No. 5,641,744 (Cooper) in view of Rieveley.

Applicants respectfully traverse these rejections as the Examiner has failed to make out a *prima facie* case of obviousness. As stated in MPEP §2143.03: "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." (Citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).) In the instant case, the Examiner has not cited where in the prior art each of the claim limitations is either taught or suggested.

More specifically, with regard to claims 2 and 3, the Examiner has not addressed the limitations of "an insulin analog that binds an insulin receptor and lowers blood glucose and that differs from a naturally occurring insulin by one or more amino acid differences, and a physiologically active fragment of said insulin analog". In addition, with regard to claim 21, the Examiner has not addressed the limitations of "at least one agent selected from the group consisting of an insulin-related peptide, an insulin-related peptide analog, a physiologically active insulin-related peptide fragment and a physiologically active insulin-related peptide analog fragment" wherein said agent "comprises a hydrophobic portion that is coated with a pharmaceutically acceptable non-ionic surfactant that is a block copolymer of propylene oxide and ethylene oxide".

Because claims 2 and 3 each incorporate all of the limitations of claim 1 from which they depend, these claims cannot be found obvious under 35 U.S.C. §103 unless the prior art teaches or suggests each of these limitations. Likewise, claim 21 cannot be found obvious unless the prior art teaches or suggests each limitation of that claim.

In view of the failure to make out a *prima facie* case of obviousness for any of the pending claims, withdrawal of the rejections based on 35 U.S.C. §103 is respectfully requested.

**VII. Conclusion**

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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